



November 21, 2011

**Notes on  
Proposed Review Process for the [13<sup>th</sup>] Report on Carcinogens<sup>1</sup>**

#	Process Element		Likely Effect On:		
			Transparency	ORoC 'Efficiency' <sup>2</sup>	Publication Timeliness
1	Nominations from 'federal partners'	No	None	None	None
2	Nominations from the public	No	None	None	None
3	Initial ORoC evaluation	No	None	None	None
	—Shared with 'federal partners'	Yes?	Unclear; not formally part of current process	None or negative	None or negative
	—Not shared with public	No	None; key missed opportunity	None	None
4	ORoC produces 'concept papers'	?	Unclear; content ambiguous	Unclear; content ambiguous	Unclear; content ambiguous

<sup>1</sup> National Toxicology Program, *Federal Register* 76 (210):67200.

<sup>2</sup> "Efficiency" is not defined in the proposal, but it must mean something different than "enable the NTP to publish the RoC in a timelier manner," which is separately listed as a goal; see note 1. I assume that it means reducing unproductive activity within ORoC that does not (or could not) improve scientific quality.

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#	Process Element		Likely Effect On:		
			Transparency	ORoC 'Efficiency' <sup>2</sup>	Publication Timeliness
5	BSC review of 'concept papers' for (1) 'rationale' and (2) 'proposed approach' for ORoC review	Yes	Unclear; depends on charge, BSC action, and NTP response	Unclear; depends on charge, BSC action, and NTP response	Unclear; depends on charge, BSC action, and NTP response
6	BSC review of 'concept papers' excludes review of public comments	No	None; key missed opportunity	None; key missed opportunity	None; key missed opportunity
7	No NTP response to public comments on 'concept papers'	No	None; key missed opportunity	None; key missed opportunity	None; key missed opportunity
8	NTP may defer or terminate review at any time	No	None	None	None
9	Draft 'cancer evaluation component' of 'ROC Monograph' <sup>3</sup>	?	Unclear; is this the same as the existing 'background document'?	Unclear	Unclear

<sup>3</sup> The "RoC Monograph appears to be like an IARC Monograph, but it is hard to tell given the limited information disclosed.



#	Process Element		Likely Effect On:		
		Change?	Transparency	ORoC 'Efficiency' <sup>2</sup>	Publication Timeliness
10	Process now 'tailored to enable ORoC to use the most appropriate mechanism(s) to obtain external advice and address scientific issues', 'may vary across substances'	Yes	Negative; 'tailored' process is ad hoc, inherently unpredictable, and highly susceptible to nonscientific considerations	Unclear	Negative; very likely to increase controversy
11	Listing criteria unchanged	No	None; key missed opportunity	None; key missed opportunity	None; key missed opportunity
12	Prepare draft substance profile; combine with 'cancer evaluation component' to produce 'RoC Monograph'	No	None	None	None
13	Public release of draft 'Roc Monograph' for public comment	No	None	None	None

#	Process Element		Likely Effect On:		
			Transparency	ORoC 'Efficiency' <sup>2</sup>	Publication Timeliness
14	Peer review of draft 'RoC Mono-graph' by BSC <u>or ad hoc 'expert panels'</u>	Yes	Depends on peer review procedures	Depends on peer review procedures	Depends on peer review procedures
	—Do ad hoc panels have more expertise than BSC? <sup>4</sup>	?	None	<u>Positive</u> if ad hoc panels have more expertise than BSC  <u>Negative</u> if ad hoc panels lack requisite expertise and independence	<u>Positive</u> if ad hoc panels have more expertise than BSC  <u>Negative</u> if ad hoc panels lack requisite expertise and independence
	—Public comments excluded from peer review	No	None; key missed opportunity	None; key missed opportunity	None; key missed opportunity
	—Text of peer review charge is different but appears unchanged <sup>5</sup>	No?	None; key missed opportunity	None; key missed opportunity	None; key missed opportunity

<sup>4</sup> As a standing FACA advisory committee, the BSC may (and probably do) not have the requisite expertise to effectively peer review all proposed listings that come before it.

<sup>5</sup> Current: "The BSC is charged to determine whether the scientific information cited in the draft substance profile for a candidate substance is technically correct, clearly stated and supports the NTP's policy decision regarding its listing in the RoC. The BSC is not asked to review the NTP's decision regarding listing status." Proposed: "The peer review charge is twofold: (1) to comment on the cancer evaluation component, specifically, whether it is technically correct and clearly stated, whether the NTP has objectively presented and assessed the scientific evidence, and whether the scientific evidence is adequate for applying the listing criteria, and (2) to comment on the substance profile, specifically, whether the scientific justification presented in the substance profile supports the NTP's preliminary policy decision on the listing status of the candidate substance in the RoC



#	Process Element		Likely Effect On:		
			Transparency	ORoC 'Efficiency' <sup>2</sup>	Publication Timeliness
15	NTP responds to peer review report	No	None; key missed opportunity	None; key missed opportunity	None; key missed opportunity
16	NTP response to public comment eliminated	Yes	Negative	Unclear; depends on meaning of 'efficiency'	Negative; very likely to increase controversy
17	NTP finalizes 'RoC Monograph'	No	None	None	None